K013866

DEC 1 4 2001

Attachment 4
510(k) Summary

Category:	Comments
Sponsor:	Boston Scientific Corporation 2710 Orchard Parkway San Jose, CA 95134
Correspondent:	Andrea L. Ruth Senior Associate, Regulatory Affairs 2710 Orchard Parkway San Jose, CA 95134
Contact Information:	E-mail: rutha@bsci.com Phone: 408.895.3625 Fax: 408.895.2202
Device Common Name	Intracardiac Introducing Sheaths
Device Proprietary Name	Convoy™ Advanced Delivery Sheath Kit
Device Classification	Class II, DRF 21 CFR §870.1340
Predicate Device	Intracardiac Introducing Sheaths
Predicate Device Manufacturer(s)	Boston Scientific Corporation
Predicate Device Proprietary Name(s)	Soft Tip Sheath Kit
Predicate Device Classification Number	Class II, DRF 21 CFR §870.1340

Date Summary Was Prepared:

November 20, 2001

Description of the Device:

The Soft Tip Intracardiac Introducing Sheath Kit consist of: (1) a disposable Introducer Sheath, (2) a Vessel Dilator and (3) Guidewire with Guidewire Introducer. These devices are designed for the introduction of various types of cardiovascular catheters to the heart.

The Introducer Sheaths are constructed in a range of curve reach configurations, diameters and lengths to respond to physician preferences. The Introducer Sheath configurations covered under the subject 510(k) Premarket Notification include 8.5 F and 9.5 F diameter, angles ranging from 0° - 180°, radius of curvatures ranging from 0.6" - 1.75", lengths of 60 cm - 101.5 cm, and may be configured with either one, two or three curves in a single or dual plane.

Intended Use:

The Boston Scientific/EP Technologies Convoy Advanced Delivery Sheaths and accessories are designed to facilitate the intracardiac placement of interventional devices. The sheath may be exchanged and used in a transseptal position after transseptal puncture has been obtained using a different sheath.

Comparison to Predicate Device:

	Predicate Device	Modified Device
510(k) Reference	K992309	Current Submission
Intended Use	Intracardiac Placement of Interventional Devices	Same
Device Description	Intracardiac Introducing Sheath	Same
Single Use?	Yes	Same
EO Sterilized?	Yes	Same
Manufacturer	BSC/EPT	Same
Device Classification	Class II, DRF; 21 CFR §870.1340	Same

Summary of the Non-clinical Data:

Where appropriate, testing conformed to the requirements of 21 CFR Part 58 (Good Laboratory Practices (GLP)). Non-clinical tests conducted for the Sheath demonstrated substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 4 2001

Ms. Andrea L. Ruth
Senior Associate, Regulatory Affairs
Boston Scientific Corporation
c/o EP Technologies, Inc.
2710 Orchard Parkway
San Jose, CA 95134

Re: K013866
Convoy Advanced Delivery Sheath Kit
Regulation Number: 870.1340
Regulation Name: Catheter introducer.
Regulatory Class: Class II
Product Code: DBY
Dated: November 20, 2001
Received: November 21, 2001

Dear Ms. Ruth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2
Intended Use Statement

510(k) Number (if known): K013866

Device Name: Convoy™ Advanced Delivery Sheath Kit

Indication for Use:

The Boston Scientific/EP Technologies Convoy™ Advanced Delivery Sheaths and accessories are designed to facilitate the intracardiac placement of interventional devices. The sheath may be exchanged and used in a transseptal position after transseptal puncture has been obtained using a different sheath.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013866

Prescription Use ✓ OR Over-the-Counter Use_____

(Per 21 CFR §801.109)

(Optional Format 1-2-96)